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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,965	11/07/2005	Stefan Golz	Le A 36 374	8345

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EXAMINER	
SHEN, BIN	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
03/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,965	GOLZ ET AL.	
	Examiner	Art Unit	
	BIN SHEN	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,27 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2, 27, 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 2, 28 stand rejected under 35 U.S.C. 102(b) as being anticipated by Fujishige et al. (JBC 1999;274:18438-18445).

Fujishige et al. teach a method of determining the activity of a PDE10A polypeptide at a certain concentration and at a different concentration of several test compounds (page 18443, right column, last paragraph and Table II). Table II shows the IC50 value of the tested compounds/inhibitors. A test compound (inhibitor) needs to be tested at several different concentrations in order to obtain an accurate IC50 value. The method also identifies test compound as a potential therapeutic agent useful in the treatment of cardiovascular disease, and other diseases involve the tissue/organ where PDE10A is expressed, (see expression of human PDE10A in various tissues such as heart that related to cardiovascular disease and brain that related to Alzheimer's disease, on page 18442, Fig. 3) because the only nexus between PDE10A and various diseases claimed in the specification is the tissue specific expression patterns which is shown by Fujishige in Fig.3 on page 18442. Therefore, the cited reference is deemed to anticipate the instant claims above.

Applicant's arguments filed 1/8/2008 have been fully considered but they are not persuasive.

Applicant argues that Fujishige does not expressly or inherently describe identifying a test compound as a potential therapeutic agent useful in the treatment of a cardiovascular disease and/or Alzheimer's disease.

It is the examiner's position that Fujishige teaches all the steps in the claimed screening method, and "useful in the treatment of a cardiovascular disease and/or Alzheimer's disease" are functional languages directed to intended use for the agents obtained after performing the

screening method. That is, it is an interpretation of the results, comprising nothing more than mental steps.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 2, 27, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujishige.

Fujishige teaches what is above.

Fujishige does not teach identifying test compound as a potential therapeutic agent useful in the treatment of cancer.

However, Fujishige suggest a link between the tissue specific expression pattern of PDE10A and genetic disease (such as juvenile parkinsonism, see page 18445, left column, end of 1st full paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of Fujishige to identify compound as a potential therapeutic agent useful in the treatment of many diseases involved in the tissue/organ where PDE10A expresses because Fujishige teaches a method of screening for therapeutic agents (read as inhibitors) that affect PDE10A activity and identify the compound (inhibitor) as potential therapeutic agent useful in the treatment of diseases by showing PDE10A's tissue specific expression pattern. One would have been motivated to use the method to identify compound as a potential therapeutic agent for cancer and other diseases because Fujishige et al. specifically described the link between PDE10A expression pattern and genetic disease (page 18445, left column, end of 1st full paragraph), and would reasonably have expected success in view of Fujishige's suggestion of

analysis of tissue distribution in detail for pharmacological analysis using selective inhibitors to elucidate its physiological role (page 18445, left column, 2nd full paragraph).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments filed 1/8/2008 have been fully considered but they are not persuasive.

Applicant argues that Fujishige does not expressly or inherently describe identifying a test compound as a potential therapeutic agent useful in the treatment of a cardiovascular disease and/or cancer, liver disease, diabetes and kidney disease, Alzheimer's disease.

It is the examiner's position that Fujishige teaches all the steps in the claimed screening method, and "useful in the treatment of a disease "(all the disease claimed in claims 2, 27, 28) are functional languages directed to intended use for the agents obtained after performing the screening method. Furthermore, since all the claims directed to screening method not method of treatment, thus the tissue specific expression patterns of PDE10A are not directly related with the screening method, but merely provide possible uses for the screened agents.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claim is allowed.

Certain papers related to this application may be submitted to Art Unit 1657 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, Ph.D., whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday,

from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571) 272-0925.

B Shen

Art Unit 1657

/Jon P Weber/

Supervisory Patent Examiner, Art Unit 1657